

REMARKS

Status of the Claims.

Claims 1, 8, 17-36, 38-57, 97, 104, and 113-117 are pending with entry of this amendment, claims 2-7, 9-16, 58-96, 98-103, 105-112 being cancelled and no claims being added herein. Claims 1, 17-22, 29-36, 97 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (*e.g.*, in the claims as originally filed).

Election/Restriction.

Pursuant to a restriction requirement made final, Applicants cancel claims 58-96, and 118 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

Applicants note, however, **the Examiner's handling of the election of Group I in the response filed on August 31, 2005 is improper.** Contrary to the Examiner's assertion, independent claims 1, 36, 97 are **linking claims**. Moreover, as stated in the response filed on August 31, 2005, **claims 1, 3, 8, 17-57, 97, 99, 104, and 113-117 read on the elected species.** Accordingly, withdrawal of claims 2-7, 9-16, 58-96, 98-103, 105-112, and 118 from further consideration is improper and these claims should be reunited.

35 U.S.C. §112, second paragraph:

Claims 97, 104, and 113-117 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because of the recitation of "plurality". Applicants traverse.

The term "plurality" is routinely used in claims drafting to refer to "two or more" (*see, e.g.*, Landis on Mechanics of Patent Claim Drafting, Fourth Edition, Section 20, page III-17). Moreover, we note that as of June 22, 2006, **the term "plurality" is used in the claims of 1,060,333 issued patents.** The term is clearly of standard usage, and completely informs one of skill of the metes and bounds of the claims. Accordingly the rejection under 35 U.S.C. §112, second paragraph, on these grounds should be withdrawn.

Claims 97 and 104 were rejected under 35 U.S.C. §112, second paragraph, as allegedly lacking antecedent basis in the recitation of "an antibody". For the purposes of clarity, claim 97 is amended to recite ". . . wherein said antibody is a botulinum neurotoxin type A antibody that neutralizes BoNT/A thereby clarifying what "an antibody" refers to and obviating this rejection.

35 U.S.C. §102:

Claims 1, 8, 24, 25-57, 97, and 104 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Amersdorfer *et al.* (1997) *Infection and Immunity* 65(9): 3743-3752. Claims 1, 8, 24, 25-57, 97, and 104 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Chen *et al.* (1997) *Infection and Immunity*, 65(5): 1626-1630. Claims 1, 8, 17-22, 29-46, 50-57, 97, 104, and 113-117 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Amersdorfer *et al.* (2002) *Vaccine*, 20: 1640-1648, or Mullaney *et al.* (2001) *Infection and Immunity*, 69(10): 6511-6514. Claims 1, 8, 17-22, 29-46, 50-57, 97, 104, and 113-117 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Baravi *et al.* (2002) *Vaccine*, 20: 1640-1648. Applicants traverse.

The Examiner is respectfully reminded that the priority date of the present application is **August 31, 1998**. As clearly stated in paragraph 0001 of the application:

[0001] This application claims priority to and benefit of USSN 60/400,721, filed on August 1, 2002, and is also a continuation-in-part of USSN 09/144,886, filed on **August 31, 1998**, both of which are incorporated herein by reference in their entirety for all purposes.

The following references cited by the Examiner were published after the priority date of the present application or less than one year before the priority date and are therefore unavailable as prior art under 35 U.S.C. §102(b):

Amersdorfer *et al.* (1997) *Infection and Immunity* 65(9): 3743-3752

Amersdorfer *et al.* (2002) *Vaccine*, 20: 1640-1648

Mullaney *et al.* (2001) *Infection and Immunity*, 69(10): 6511-6514

Baravi *et al.* (2002) *Vaccine*, 20: 1640-1648.

Accordingly, the rejections under 35 U.S.C. §102(b) in light of these references are improper and should be withdrawn.

With respect to the citation of Chen et al. (supra) the Examiner is respectfully reminded that anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

In the instant case, claims 1, 8, and 17-35, as amended herein are directed to:

1. An isolated **human** antibody that specifically binds to an epitope specifically bound by an antibody expressed by clone huC25, wherein said antibody binds to and neutralizes botulinum neurotoxin type A (BoNT/A).

The antibodies described by Chen *et al.* are derived from three libraries: two mouse libraries, and one human library (*see, e.g.*, page 1627, col. 1). The Examiner has failed to establish that antibodies produced from the human library by Chen *et al.* specifically bind to an epitope bound by an antibody expressed by clone huC25. Indeed, it is noted that neither C25 nor huC25 are disclosed by Chen *et al.*

Moreover, Chen *et al.* also fail to test for and establish that any of the antibodies described therein neutralize botulinum neurotoxin type A as recited in claim 1. Accordingly, all the limitations of claims 1, 8, and 17-35 are not met by Chen *et al.* and the rejection of these claims under 35 U.S.C. §102(b) on these grounds should be withdrawn.

Claims 36, and 38-57 are drawn to:

36. An isolated anti-botulinum neurotoxin type A (anti-BoNT/A) antibody, said antibody comprising a variable heavy (V_H) complementarity determining region (CDR) listed in Table 4, Table 9, or Table 11, and wherein said antibody specifically binds to and neutralizes a botulinum neurotoxin type A, wherein said antibody binds both an A1 and an A2 toxin.

Chen *et al.* does not test for and fails to teach that any of the antibodies disclosed therein bind to both an A1 and an A2 toxin. Accordingly, all the limitations of claims 36, and 38-57 are not met by Chen *et al.* and the rejection of these claims under 35 U.S.C. §102(b) on these grounds should be withdrawn.

Claims 97, 104, and 113-115 as amended herein, are drawn to a method of making an anti-BoNT/A antibody that neutralized BoNT/A where the method involves:

... contacting a plurality of antibodies with an epitope specifically bound by an antibody expressed by clone huC25; and isolating an antibody that specifically binds to said epitope, wherein said antibody is a botulinum neurotoxin type A antibody that neutralizes BoNT/A. [emphasis added] (see claim 97)

Chen *et al.* fail to disclose a C25 or huC25 antibody and thus fail to disclose a method of making an antibody that involves isolating an antibody that specifically binds the epitope recognized by huC25 as recited in claim 97. Thus, all the limitations of claims 97, 104, and 113-115 are not met by Chen *et al.* and the rejection of these claims under 35 U.S.C. §102(b) in light of Chen *et al.* should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

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Respectfully submitted,



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